DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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May 20, 2015

Reckitt Benckiser
Elizabeth Torre
Regulatory Operations Lead
Morris Corporate Center IV
399 Interpace Parkway
Parsippany, NJ 07054

Re: K143511
Trade/Device Name: K-Y® Brand Touch® All-in-One Warming Caressing Crème and Personal Lubricant
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: April 21, 2015
Received: April 27, 2015

Dear Elizabeth Torre,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143511

Device Name
K-Y® BRAND TOUCH® All-in-One Warming Caressing Crème and Personal Lubricant

Indications for Use *(Describe)*
K-Y® BRAND TOUCH® All-in-One Warming Caressing Crème and Personal Lubricant is a personal lubricant, for penile and/or vaginal application, intended to lubricate and enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is not compatible with natural rubber latex, polyisoprene, or polyurethane condoms.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Submitted by:	Reckitt Benckiser LLC Morris Corporate Center IV 399 Interpace Parkway Parsippany, NJ 07054 Phone: (973) 404-2715
Contact Person:	Elizabeth Torre, MPH Regulatory Operations Lead, Reckitt Benckiser LLC

Date Prepared:	December 14, 2014
Proprietary Name(s):	K-Y® BRAND TOUCH® All-in-One Warming Creme and Personal Lubricant
510(k) Number:	K143511
Classification Name:	Condom (21 CFR §884.5300); Class II
Product Code:	NUC (lubricant, personal)
Cleared Device/Predicate:	K081236 K-Y® Brand Intrigue™ 2-in-1 Massage Creme™

Indication for Use:
K-Y® BRAND TOUCH® All-in-One Warming Caressing Crème and Personal Lubricant is a personal lubricant, for penile and/or vaginal application, intended to lubricate and enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is not compatible with natural rubber latex, polyisoprene, or polyurethane condoms.

Description of the Device:

K-Y® BRAND TOUCH® All-in-One Warming Caressing Creme and Personal Lubricant, is a non-sterile, anhydrous, fragranced, glycol-in-silicone emulsion that provides a warming sensation upon contact with ambient moisture on the skin. It is composed of a combination of lubricants and emollients, an antioxidant, a gelling agent, a thickener, a film former, a stabilizer, a surfactant, and a fragrance. The emulsion is off-white to beige in color with a slight hint of vanilla and/or floral scent. It has a viscosity, specific gravity, and lubricity typical for emulsions of this type.

The product will be filled in printed black 3.0 ounce high density polyethylene (HDPE) heart shaped bottles, sealed with black pump closures, and packaged in printed cartons.

Like the cleared device, the modified device, K-Y® BRAND TOUCH® All-in-One Warming Caressing Creme and Personal Lubricant, will be marketed as a non-prescription medical device for over-the-counter (OTC) use.

Technological Characteristics

The modified device, K-Y® BRAND TOUCH® All-in-One Warming Caressing Creme and Personal Lubricant, is substantially equivalent to the cleared device. The intended use is identical and the technical characteristics vary only slightly due to the addition of small amount of fragrance. Aside from the fragrance, all of the ingredients in the modified device are identical, and they are present at almost identical concentrations to those in the cleared device.

Performance Data:

Biocompatibility

K-Y® BRAND TOUCH® All-in-One Warming Caressing Creme and Personal Lubricant is varied slightly from the cleared predicate device; the only difference in the formula is the addition of a fragrance. All of the ingredients, except the fragrance, have been used in other 510k cleared marketed devices.

Biocompatibility evaluation of the K-Y® BRAND TOUCH® All-in-One Warming Caressing Creme and Personal Lubricant consisted of the following tests:

- Cytotoxicity according to ISO 10993-5:2009
- Guinea Pig Maximization Sensitization according to ISO 10993-10:2010
- Vaginal Irritation according to ISO 10993-10:2010
- Acute Systemic Toxicity according to ISO 10993-11:2006

The results of these tests demonstrate that the K-Y® BRAND TOUCH® All-in-One Warming Caressing Creme and Personal Lubricant is biocompatible.

Condom Compatibility

Condom compatibility testing was conducted in accordance with ASTM D7661-10. Under current standards, the modified device may have an effect on the mechanical and/or physical integrity of natural rubber latex, synthetic polyisoprene and polyurethane condoms. Therefore, condom compatibility claims are not requested for this modified device.

Stability:

Shelf life testing was conducted on final devices to support the targeted two-year shelf-life. Based on satisfactory results of this testing, the product will be labeled with a 2 year expiration date.

Conclusion

Because the minor modifications (i.e., fragrance) to this cleared device do not raise new types of questions of safety or effectiveness, there is no change in intended use or fundamental scientific technology, and the results of additional technological characterization, biocompatibility testing, and performance testing are favorable, we conclude that the modified device, K-Y® BRAND TOUCH® All-in-One Warming Caressing Creme and Personal Lubricant, is substantially equivalent to our legally cleared predicate device, K-Y® Brand Intrigue™ 2-in-1 Massage Creme™.